REMARKS

Claims 62-69 are under prosecution in this case with the entry of this Amendment. All the pending claims (claims 21-26, 29, 34-39, and 40) have been canceled without prejudice. New claims 62-69 have been entered to better claim the subject matter which Applicants regard as the invention and for improved clarity. Support is found throughout the as-filed Specification, particularly in the as-filed claims 1-10 and 16-17. Therefore, none of the amendments made herein represents the addition of new matter.

Claim Objections:

Claim 21 is objected to based on the allegation that it introduces new matter. Claim 21 has been canceled without prejudice in this Amendment. Accordingly, this objection becomes moot with the entry of the present Amendment.

Claim Rejections under 35 U.S.C. § 112:

Claims 21-26, 34-38, and 40 are rejected under 35 U.S.C. § 112, second paragraph, as allegedly indefinite based on the usage of certain terms in the claims. Without acquiescing to the proprietary of this rejection and in the interest of advancing the prosecution of this application, the rejected claims have been canceled without prejudice. Claims 62-69 as entered herein do not recite the terms at issue with the following exception.

Applicants maintain that the terms, "inactivated or attenuated" as recited in claim 62, are commonly used in the art and their meaning is readily understood by a skilled artisan. For example, "inactivation" is defined as 'the process of destroying or removing the activity of an agent or substance" and "attenuation" is defined as "diminution of virulence in a strain of organism" (*see* Stedman's Medical Dictionary, 26th Edition, Williams & Wilkins, A Waverly Company). These terms as used in the invention are intended to mean exactly as defined and understood by a person of ordinary skill in the art. An inactivated virus of the invention is non-infectious and replication defective. Furthermore, the as-filed Specification provides a specific example of how the influenza

virus was inactivated using formalin under certain conditions and the inactivation was confirmed by the *in vitro* plaque assay and *in vivo* inoculation (*see* Example 2 on page 20).

Based on the foregoing, claims 62-69 are considered to be definite and clear. Withdrawal of the rejection under 35 U.S.C. § 112, second paragraph, is respectfully requested.

Claim Rejection under 35 U.S.C. § 112:

Claims 21-26, 34-38, and 40 remain rejected under 35 U.S.C. § 112, first paragraph, on the ground that the Specification allegedly does not enable any person skilled in the art to make and/or use the invention commensurate in scope with these claims.

Without acquiescing to this aspect of the rejection and in the interest of advancing prosecution of this application, the rejected claims have been canceled without prejudice.

Applicants submit that the new claims entered (62-69) are based on the inventor's discovery that the immune response can be induced in CD4+ T cell independent manner, contrary to the general belief in the field at the time when the present application was filed. The state of the knowledge at that time was as such that CD4+ T cells are believed to be essential for inducing immune response. Thus, the invention provides a new means of inducing immune response in a subject who has a deficiency in CD4+ T cells.

Based on the foregoing, it is submitted that the rejection under 35 U.S.C. § 112, first paragraph, is no longer applicable for claims 62-69. Withdrawal of the rejection is respectfully requested.

Claim Rejection under 35 U.S.C. § 102:

Claims 21-26, 34-38, and 40 stand rejected under 35 U.S.C. § 102(b) as allegedly anticipated by Compans, Pertmer et al., Muster et al., Pales et al., Li et al., and Chiba et al.

Without acquiescing to the propriety of this rejection and in the interest of advancing prosecution of this application, the rejected claims have been canceled without prejudice.

Applicants submit that the newly entered claims 62-69 are not anticipated by any of the cited references. The present invention claims a method for inducing immune response, not a composition, and thus the claims specifically define limitations relevant for making and using the invention. None of the cited art teaches or suggests such method. The invention is a new method of inducing a humoral immune response in a subject deficient in CD4 T cells by administering a certain antigen (e.g., inactivated virus) that is not infectious to the subject. Nothing in the cited art mentions a link to such compromised condition of CD4 T cell deficient subjects. This invention was based on the inventor's discovery that protective immune responses were observed when the formalin-treated (i.e., inactivated) influenza virus was administered into mice deficient in CD4 T cells prior to challenging such mice with live influenza virus. This discovery was unexpected because it was believed that the CD4+ T cells were necessary for developing humoral immune response and that such immune protection could not be achieved. Therefore, this invention provides a new means of inducing immune response, i.e., immune protection for CD4 T cell deficient subjects, which was viewed not possible previously.

Based on the foregoing, Applicants submit that none of the cited references are relevant in view of the amended claims submitted herewith. Withdrawal of the rejection under 35 U.S.C. § 102(b) is respectfully requested.

Claim Rejection under 35 U.S.C. § 112:

Claim 21 as amended is rejected under 35 U.S.C. § 112, first paragraph, as allegedly containing new subject matter. Without acquiescing to this rejection, claim 21 has been canceled without prejudice. Thus, this rejection is no longer relevant and should be removed.

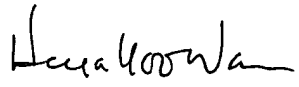
CONCLUSION

Based on the foregoing amendments and arguments, this application is considered to be in condition for allowance, and passage to issuance is respectfully requested.

If there are any outstanding issues related to patentability, the courtesy of a telephone interview is requested, and the examiner is invited to call to arrange a mutually convenient time.

This Amendment is accompanied by a Request for Continued Examination and the necessary fee. It is believed that no additional fee is required for this submission. If this is incorrect, however, please charge any deficiency or any fee necessary for extension of time to Deposit Account No. 07-1969.

Respectfully submitted,



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